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IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Motion Day: November 19, 2012 **Oral Argument Requested**

MEMORANDUM IN SUPPORT OF HANMI'S MOTION TO AMEND ITS CONTENTIONS

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Pursuant to Local Patent Rules 3.6 and 3.7, Defendants Hamni USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. (collectively "Hanmi"), respectfully submit this Memorandum in Support of Hanmi's Motion to Amend Its Contentions. Hanmi's second amended contentions are attached as Exhibit A to the Declaration of Mayra V. Tarantino ("Tarantino Dec.") in redline form based on Hanmi's last-served contentions dated December 9, 2011. By email on October 11, 2012, Hanmi provided Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca") with Hanmi's draft of the proposed amendment and inquired whether AstraZeneca would consent to this motion. On October 15, 2012, AstraZenceca responded that it opposes the amendment.

I. INTRODUCTION AND BRIEF SUMMARY

Hanmi seeks leave to amend to assert non-infringement of the asserted claims of the '504 and '192 patents-in-suit, based on AstraZeneca's position in opposition to Hanmi's Motion for Summary Judgment No. 4 (relating to invalidity due to hydrate scope), and the Court's August 30, 2012 Opinion (D.I. 233). Hanmi should be permitted to show that its proposed tetrahydrate product does not infringe the claims literally or under the doctrine of equivalents.

In the alternative, if the Court denies the amendment asserting the grounds of non-infringement proposed, Hanmi respectfully asks that its proposed amendment be permitted to the extent it addresses the "hydrates" invalidity defenses raised in Motion No. 4, in light of AstraZeneca's position and the Court's ruling. In particular, Hanmi's amendment should be permitted to bar AstraZeneca from asserting that Hanmi's defenses raised in Motion No. 4 are foreclosed by the Court's ruling in D.I. 233, and Hanmi identifies issues reserved for trial that were raised by the summary judgment record.

II. HANMI HAS SHOWN GOOD CAUSE FOR PERMITTING THE PROPOSED AMENDMENT

Section 3.7 of the Local Civil Rules, among the exemplary instances that call for the issuance of Court order to amend, provides:

> (a) a claim construction by the Court different from that proposed by the party seeking amendment …
>
> (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement … that requires response by the adverse party because it was not previously or reasonably anticipated.

The Court has recognized that "Rule 3.7 is not a straightjacket into which litigants are locked from the moment their contentions are served" and that "while the Local Patent Rules strive to have a party establish its contentions early on, it is important to recognize that preliminary infringement contentions are still preliminary." *See TFH Pubs., Inc., v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010) (quotation marks, citations, and brackets omitted).

Courts having implemented patent rules expressly recognize that such frameworks contemplate amendment of contentions. *Mediostream, Inc. v. Microsoft Corp.*, Civil Action No. 2:08-cv-369-CE, 201 WL 4118589 at *1 (E.D. Tex. Oct. 18, 2010); *Alt v. Medtronic, Inc.*, 2006 U.S. Dist. LEXIS 4435 at *1 (E.D. Tex. Feb. 1, 2006) (granting motion to amend invalidity contentions in light of plaintiff's shifting case theories).[1] Courts have broad discretion to allow amendment of contentions. Local Patent Rule 3.7 provides non-exhaustive examples of grounds for good cause, absent undue prejudice to the adverse party. As noted above, these include an

[1] Because this district and the Eastern District of Texas have adopted verbatim the Local Patent Rules of the Northern District of California, the Court may look to cases from those districts for guidance. *TFH Pubs., Inc.*, 705 F. Supp. 2d at 365 n.3.

adverse claim construction or disclosure of a contention by a Hatch-Waxman party asserting infringement under L. Pat. R. 3.6(g) that requires a response by the adverse party because it was not previously presented or reasonably anticipated.

In the current situation, AstraZeneca having brought suit and provided infringement contentions, Hanmi reasonably believed that AstraZeneca was asserting the '504 and '192 patents to encompass Hanmi's tetrahydrate form of esomeprazole strontium salt. However, this reasonable premise has turned out to be incorrect, based on the Court's ruling denying Summary Judgment Motion No. 4 and AstraZeneca's assertions in its opposition brief. As discussed below, this fundamental shift in the underlying premises of this litigation in light of the Court's decision and AstraZeneca's position – *i.e.*, "hydrates" are not set forth in, and are not material to the claims, and therefore do not have to be described or enabled – results in hydrates being excluded from the scope of the asserted '504 and '192 patent claims. Courts have recognized that, where a party effectively changes preliminary infringement contentions, a defendant is unable to crystallize its non-infringement and invalidity theories. *Connectel, LLC v. Cisco Sys., Inc.*, 391 F. Supp. 2d 526, 528 (E.D.Tex. 2005). AstraZeneca cannot proceed to trial on a claim scope that is not enabled or described, and Hanmi therefore should be permitted to assert that its tetrahydrate product cannot infringe because claim scope has been limited by AstraZeneca's litigation position and the Court's decision. Accordingly, the proposed amendment will not impact the case schedule or the scope of discovery, or prejudice AstraZeneca; rather, Hanmi is merely conforming its present contentions (sent in draft to AstraZeneca on October 11, 2012) to the existing summary judgment record. Under these circumstances, Hanmi's request to amend its contentions is fully justified, and should be granted.

III. THE PROPOSED AMENDMENTS SHOULD BE PERMITTED

A. Because AstraZeneca Cannot Assert A Claim Scope That Is Not Enabled Or Described, The Claims Of Both Patents-In-Suit Exclude Hydrates

1. The '504 Patent

Based on the positions advanced by AstraZeneca in opposition to Hanmi's Motion for Summary Judgment No. 4 and the Court's decision relating to hydrate scope, Hanmi should be permitted to assert that its proposed product does not infringe any asserted claim of the '504 patent, because the claims do not and cannot encompass hydrated forms of the claimed salts of the (-)-enantiomer of omeprazole. *See* Tarantino Dec., Exhibit A at pp. 3, 15-26 and 36.

In its Opposition, AstraZeneca urged that:

> The '504 Patent provides written description support for the *claimed* pure solid state alkaline salts of esomeprazole *as of the filing date*. "Hydrates" is term that is simply not recited in any of the claims in this case. By imposing a written description requirement for hydrates, Hanmi contradicts fundamental patent law principles. The '504 patent also enables one of ordinary skill in the art to make and use the *claimed* pure solid state alkaline salts of esomeprazole *as of the filing date*, without undue experimentation. Hanmi's attempt to focus the enablement inquiry on "hydrates" is in violation of the prohibition on importing limitations into the claims—the claims in the '504 Patent are not limited to "hydrates."

D.I. 153, page 2.

AstraZeneca further urged that:

> First, Hanmi is improperly importing a "hydrates" limitation into the claim language which case law prohibits. It is established law that limitations cannot be imported into claimed subject matter.

D.I. 153, page 4. AstraZeneca went on to argue:

> Hanmi's premise that there is a "hydrates issue" is not relevant to an enablement inquiry, because the scope of the '504 Patent claims is not limited to hydrates and the so-called "hydrates issue" is based on technology not in existence as of the filing date of the '504 Patent claims.

D.I. 153, pages 12-13. In arguing against Hanmi's non-enablement position, AstraZeneca told the Court regarding *Wands* factors that:

> The predictability or unpredictability of which hydrate may or may not form is not relevant to this analysis.

D.I. 153, page 14. AstraZeneca stated that:

> Hanmi argues that "there is no disclosure in the'504 Patent specification that describes any hydrate form of a esomeprazole salt, the production of hydrated salt forms, or the manner and process of making a hydrated form of the claimed alkaline salts of esomeprazole." (Defs.' Br. Summ. J. 2.) This premise, however, is entirely incorrect, as a matter of law, and thus, has no relevance to the enablement inquiry.
>
> The '504 Patent enables one of ordinary skill in the art to make and use the claimed pure solid state alkaline salts of esomeprazole as of the filing date, without undue experimentation. Hanmi's attempt to focus the enablement inquiry on "hydrates" is in violation of the prohibition on importing limitations into the claims—the claims in the '504 Patent are not limited to "hydrates."
>
> * * *
>
> Accordingly, the entire premise of Hanmi's arguments concerning the "'hydrates' issue" is completely incorrect as a matter of law because this issue is inapposite to an enablement inquiry relating to claimed subject matter of the '504 Patent as of the filing date.

D.I. 153, pages 15-16.

AstraZeneca's opposition tried to straddle the fence by asserting on the one hand that Hanmi was "importing a hydrates limitation into the claims," while on the other hand appearing to argue that the claims were generic to hydrates and other species (*see* D.I. 153, page 4: "None of the claims in the '504 Patent is limited to "hydrates," and thus Hanmi's inquiry focused only on this subset is improper."). Yet, AstraZeneca appeared to persuade the Court that hydrates are outside the scope of the asserted claims, based on the Court's ruling on Motion No. 4. In particular, the Court's August 30, 2012 Opinion sided with AstraZeneca's various positions referenced above, in concluding that "Hanmi has not convinced the Court that 'hydrates' are material to the written description or enablement inquiry, ***as such inquiries relate only to those matters set forth in the claims***." D.I. 233, page 19 (emphasis added).

The Court's decision and AstraZeneca's position that "hydrates" are not set forth in the claims, and therefore do not have to be described or enabled, results in hydrates being excluded from the scope of the asserted '504 patent claims, and not generically encompassed by them. Thus, Hanmi should be permitted to assert that its tetrahydrate product cannot infringe, because claim scope has been limited by AstraZeneca's litigation position, and the Court's ruling.

AstraZeneca cannot proceed to trial on a claim scope which is not enabled or described. In Hanmi's summary judgment reply brief, Hanmi urged in response to AstraZeneca's above-referenced positions that AstraZeneca cannot have it both ways – that since the claims were asserted by AstraZeneca to encompass hydrates, hydrated forms must be enabled as of the filing date under well-settled Federal Circuit precedent demanding ***full scope*** enablement. D.I. 168, pages 9-11 (citing *AK Steel*, *Plant Genetic* and *Liebel-Flarsheim*, each discussed below). Since the Court did not mention or distinguish Hanmi's full scope enablement precedent, and viewed hydrates as not "material" to enablement and written description, and not "set forth in the claims," the result on the present record is that the scope of each asserted claim of the '504 patent excludes hydrates.

To be clear, any interpretation of the Court's ruling on Motion No. 4 which results in the claims-in-suit not having to be enabled *because they do not expressly recite an element (such as hydrates) even though asserted to be generically encompassed* – which is apparently the result AstraZeneca seeks – would be fundamentally contrary to Federal Circuit precedent. Clear Federal Circuit authority holds that ***a patent claim must be enabled over the full scope asserted against an accused infringer -- regardless of whether specific features of the accused product are recited in the claim.***

For the Court's convenience, Hanmi respectfully provides below a summary of five Federal Circuit cases that are particularly relevant to this issue of claim scope, written description, and enablement. A chart comparing the facts of each case is also provided to more clearly show the parallels in the facts of these cases to the case at bar.

In *Plant Genetic Systems v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003), claims to a transformed "plant cell" were found to be invalid for lack of enablement. Plant cells could be categorized as either "monocots" or "dicots." Neither type of plant was recited in the claims, but the claims were asserted to generically encompass both forms. All the examples in the patent were dicots (tomatoes, potatoes, etc.), but Dekalb's accused products were monocots (corn). The specification was found enabling for dicots but not for monocots – a later developed embodiment with respect to the genetic transformation at issue. The Court distinguished *In re Hogan*, 559. F.2d 595 (CCPA 1977),[2] on a variety of grounds. First, the *Plant Genetics* court stated, "We do not read *Hogan* as allowing an inventor to claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it." 315 F.3d at 1340.

The court went on to distinguish *Hogan* as a patentability decision, which didn't involve the same infringement-validity interplay of a court case:

> Moreover, *Hogan* cannot be read to assist "*improper* enforcement against later developers." Id. at 607. *Hogan* simply held that one could not use a later-existing state of the art to invalidate a patent that was enabled for what it claimed at the time of filing. In addressing the issue of whether a claim may be of sufficient breadth to cover the later state of the art, *Hogan* stated:
>
> > The business of the PTO is patentability, not infringement. Like the judicially-developed doctrine of equivalents, designed to

[2] *Hogan* was the case propounded by AstraZeneca and referenced by the Court in D.I. 233, at pp. 17-19.

> protect the patentee with respect to later-developed variations of the claimed invention, the judicially-developed "reverse doctrine of equivalents," requiring interpretation of claims in light of the specification, may be safely relied upon to preclude improper enforcement against later developers.

Id. ***If the present case were comparable to Hogan, PGS could avoid invalidation of the cell claims by at least asserting that these claims were not understood by those skilled in the art as encompassing monocots when the '236 patent was filed. However, PGS concedes that the cell claims cover monocot cells. Only by doing so can PGS sue DeKalb, which makes monocotproducts, for infringement. Having agreed that the cell claims encompass monocot cells, a later development, PGS' reliance on Hogan ignores the validity-infringement differentiation Hogan made.***

***

> We conclude that the law does not support PGS' assertion that the '236 patent is entitled to both a broad scope of coverage and a lower standard of enablement.

315 F.3d at 1341 (emphasis added). The court plainly held that if the claim generically covered transformed *monocot* cells, the specification had to enable that subject matter as of the filing date. The *Plant Genetic* case expressly recognized that the patentee's option to preserve validity was to have not asserted a monocot scope in the litigation, and that the *Hogan* case, being a Patent Office decision, simply didn't involve the interplay between infringement and validity, as occurs in infringement litigation.

In *Liebel-Flarsheim v. Medrad*, 481 F.3d 1371 (Fed. Cir. 2007), the claims related to a computer-controlled injector. The details are not relevant, except to note the claims did not expressly call for a pressure jacket (unlike the original claims as filed), but were generic to both jacketless and jacket embodiments. The specification disclosed only the jacket embodiment, yet the patent was asserted against Medrad's jacketless embodiment. The claims were found invalid for lack of enablement and written description, because the full scope of the claims as including the jacketless embodiment was not described or enabled. 481 F.3d at 1374-75.

The Federal Circuit affirmed the judgment of nonenablement, finding that full scope enablement includes the enablement of features not recited in the claims, but encompassed by the claims:

> We agree with Medrad that the district court correctly determined that the asserted claims of the front-loading patents are invalid for lack of enablement. The enablement requirement is set forth in 35 U.S.C. §112, ¶ 1 and provides in pertinent part that the specification shall describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]." We have stated that the "enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel*, 344 F.3d at 1244; *see also Wands*, 858 F.2d at 736-37.
>
> ***We have previously construed the claims of the front-loading patents such that they are not limited to an injector with a pressure jacket, and therefore the full scope of the claimed inventions includes injectors with and without a pressure jacket. That full scope must be enabled, and the district court was correct that it was not enabled.***

481 F.3d at 1378-79 (emphasis added). Any assertion by AstraZeneca that "hydrates" do not have to be enabled, because they are not expressly recited in the asserted claims, would be clearly at odds with this binding precedent, discussed in Hanmi's prior briefing, as noted above.

The *Liebel*-Flarsheim court relied on *AK Steel Corp. v. Sollac*, 344 F.3d 1234 (Fed. Cir. 2003), another highly pertinent case on full scope enablement, summing it up aptly as follows:

> The facts of this case are, in fact, more analogous to *AK Steel* than to *Spectra Physics*. In *AK* Steel, the patentee argued, as it does here, that the patent disclosed several embodiments within the properly construed claim, and that the specification need not teach the full claimed scope in order for the claims to be enabled. 344 F.3d at 1243. The claims in *AK Steel* read on steel strips containing either a Type 1 or a Type 2 aluminum coating [the claims at issue only recited an aluminum coating, not specifying the form of aluminum]. The specification clearly described only Type 2 aluminum coating. We stated, however, that "as part of the *quid pro quo* of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the *full scope of the claimed invention.*" *Id.* at 1244 (latter emphasis added).
>
> We explained that the specification need not necessarily describe how to make and use every embodiment of the invention "because the artisan's

> knowledge of the prior art and routine experimentation can often fill in the gaps." *Id.* However, because the full scope of the claims included both Type 1 and Type 2 aluminum coating, the relevant inquiry became whether one skilled in the art would have been able to make and use a steel strip containing a Type 1 aluminum coating at the time of the patent's effective filing date. *Id.* We held that the specification taught against using a Type 1 aluminum coating, and therefore that the claims were invalid for lack of enablement.
>
> Similarly, in this case, the asserted claims read on, and the full scope of the claimed invention includes, an injector system with and without a pressure jacket. There must be "reasonable enablement of the scope of the range" which, in this case, includes both injector systems with and without a pressure jacket.

481 F.3d at 1380 (matter in brackets added). AstraZeneca here is similarly situated to patentee Liebel:

> The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, "beware of what one asks for," might be applicable here.

481 F.3d at 1380.

In *ALZA Corp. v. Andrx Pharms LLC*, 603 F.3d 935 (Fed. Cir. 2010), the claims at issue encompassed both osmotic and non-osmotic dosage forms, even though neither type was expressly recited; the claim simply said "dosage form." Even non-osmotic encompassed both oral and non-oral dosage forms. Non-osmotic, non-oral dosage forms were included in the full scope of the claimed invention, were found to be not enabled by the specification, and the claims were held invalid. *See* 603 F.3d at 943 ("In this case, ALZA successfully argued to the district court that the claims encompassed both osmotic and non-osmotic dosage forms. However, ALZA's patent specification does not enable the full scope of the claims, namely non-osmotic oral dosage forms with ascending release rates.").

In *Automotive Techs. Int'l Inc. v. BMW of North America Inc.*, 501 F.3d 1274 (Fed. Cir. 2007), the claims were directed to a velocity sensor and generically covered both mechanical and electrical side impact sensors. Electrical types – even though not expressly claimed but only

generically covered – were found not enabled by the disclosure, and the claims were held invalid on summary judgment, which was affirmed on appeal. *See* 501 F.3d at 1282 ("[W]e conclude that all asserted claims 1-44 are invalid for lack of enablement because they all recite a sensor, and the full scope of the claims includes mechanical and electronic sensors, the latter of which has not been enabled."). The Court clearly viewed the full scope enablement requirement as extending to unrecited embodiments only generically covered by the claims:

> Similarly, in this case, the claim construction of the relevant claim limitation resulted in the scope of the claims including both mechanical and electronic side impact sensors. Disclosure of only mechanical side impact sensors does not permit one skilled in the art to make and use the invention as broadly as it was claimed, which includes electronic side impact sensors. Electronic side impact sensors are not just another known species of a genus consisting of sensors, but are a distinctly different sensor compared with the well-enabled mechanical side impact sensor that is fully discussed in the specification. Thus, in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both electronic and mechanical side impact sensors, which the specification fails to do.
>
> We stated in *Liebel*: "The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet." *Id.* at 1380. ATI sought to have the scope of the claims of the '253 patent include both mechanical and electronic side impact sensors. It succeeded, but then was unable to demonstrate that the claim was fully enabled. Claims must be enabled to correspond to their scope.

501 F.3d at 1285.

The following table summarizes key points from the above cases, compared against the present case:

Case	**Claim Language**	**Embodiments Covered But Not Recited**	**Result**
Plant Genetic	plant cell	monocots and dicots	dicots enabled, monocots not enabled – invalid

Liebel-Flarsheim	injector	with pressure jacket, and jacketless	Pressure jacket enabled; jacketless type was not enabled – invalid
AK Steel	aluminum coating	Type 1 Al and Type 2 Al	Type 2 enabled, Type 1 not enabled – invalid
ALZA v. Andrx	dosage form	osmotic and non-osmotic, oral and non-oral	osmotic dosage forms enabled, non-osmotic oral forms were not – invalid
Auto. Tech.	velocity sensor	mechanical and electrical sensors	mechanical sensors enabled, electrical were not – invalid
AZ v. Hanmi	salts of esomeprazole	anhydrous and hydrated forms	hydrates not recited in claims, and a scope including hydrates does not have to be enabled

Thus, under the above controlling precedent, AstraZeneca should not be permitted to proceed to trial, asserting its claims against hydrated forms of the compounds, without being required to enable or describe those forms. Nonetheless, its position that enablement is not required because hydrates are not recited in the claims, and the Court's decision confirms that hydrates must be excluded from the '504 patent's scope. Consequently, Hanmi should be entitled to assert that its proposed tetrahydrate product would not infringe the asserted claims of the '504 patent.

2. The '192 Patent

For the same reasons set forth in connection with the '504 patent above, the asserted '192 patent claims exclude hydrated forms of esomeprazole salts from their scope, because the only description of salt forms in the '192 patent is subject matter incorporated by reference from the parent '504 patent (assuming incorporation is proper in whole or in part). Thus, the '192 claims can have no broader scope than '504 with respect to hydrates. Thus, Hanmi should be permitted

to contend that none of the asserted claims of the '192 patent would be infringed by Hanmi's proposed tetrahydrate product. *See* Tarantino Dec., Exhibit A at pp. 59-60.

B. Hanmi's Proposed Amendment Should At Least Be Permitted To The Extent It Addresses The Status Of "Hydrates" Defenses Raised In Motion No. 4

In any case, should Hanmi not be permitted to amend to assert non-infringement on the above basis, the Court should allow Hanmi to amend its contentions to bar AstraZeneca from asserting that Hanmi's invalidity defenses raised in Motion No. 4 are foreclosed by the Court's ruling in D.I. 233 denying the motion. *See* Tarantino Dec., Ex. A at pages 23-26, 84, 91 and 141. The Court found that: "Moreover, given the dueling expert reports submitted and the fact that the Court must draw all reasonable inferences in light of the non-moving party, the Court finds that there exist factual issues that would preclude summary judgment in any event." D.I. 233, pages 19-20. The competing positions of the parties' experts set forth on the summary judgment record, and the parties' dispute over whether hydrates are exempted from the written description and/or enablement requirement as "later-developed technology" – an issue raised for the first time in AstraZeneca's opposition (D.I. 153) – would be issues reserved for trial. Whether hydrates can be shown to be "later-developed technology" is an entirely different issue than avoiding section 112 requirements merely because "hydrates" is not explicitly recited in the asserted claims. In this regard, AstraZeneca asserted that it was not required to enable technology that was not in existence as of the filing date. D.I. 153, pages 15-16. AstraZeneca relied primarily on the *Phillips* and *Hogan* cases, discussed at pages 17-19 of the Court's opinion (D.I. 233). The Court did not expressly exempt "hydrates" from section 112 requirements on the grounds of "later-developed technology."

AstraZeneca's "later-developed technology" position is overbroad and incorrect. AstraZeneca confuses a "later-developed *product*" (Hanmi's esomeprazole strontium

tetrahydrate) with "later-developed *technology*." Precedent makes clear that where the technology was generally known at the time of filing, such as transformed monocots in *Plant Genetic*, the narrow exception based on "later-developed technology" does not apply, and full scope enablement must be shown. Here, hydrates as polymorphic forms of pharmaceutical compounds were generally known as of the early to mid-1990s when AstraZeneca first filed for the patents-in-suit; such forms would have been desirable, and thus no exception to the full scope enablement rule exists here. *Plant Genetic*, 315 F.3d at 1340; *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247 (Fed. Cir. 2004). Hanmi's Amended Contentions contain a number of literature cites, refuting AstraZeneca's position that hydrates were "later-developed technology." *See* Tarantino Dec., Exhibit A at pp. 24-25. Indeed, as shown therein, AstraZeneca had a number of its own patents in the relevant time frame which referenced various "hydrate" forms of pharmaceutical compounds, separate from salt forms.

Even if hydrated forms of esomeprazole salts were found to be within the later-developed technology exception to the enablement requirement, that finding would have no bearing on the separate written description defense based on hydrates. In *Chiron*, a certain 1984 application was exempted from having to enable later-developed chimeric antibodies, which didn't exist at the time. Nonetheless, the court affirmed invalidity for lack of written description, because the inventors could not have had possession of, and disclosed, the subject matter of chimeric antibodies that did not even exist at the time of filing. *Chiron*, 363 F.3d at 1253-55.

IV. CONCLUSION

For the foregoing reasons, Hanmi respectfully requests that its motion be granted. A proposed Order is attached.

Dated: October 15, 2012

Respectfully,

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CERTIFICATE OF SERVICE

I, Mayra V. Tarantino, hereby certify that on October 15, 2012, I caused a copy of Hanmi's (a) Notice of Motion to Amend Contentions, (b) Memorandum in Support of Hanmi's Motion to Amend Its Contentions; (c) Declaration of Mayra V. Tarantino, (d) Form of Order, and (e) this Certificate of Service to be served on counsel for AstraZeneca through the Court's ECF system and by email.

s/Mayra V. Tarantino
Mayra V. Tarantino